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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/715,729	11/17/2003	Jean-Pierre Sommadossi	06171.105062	5135

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EXAMINER	
HUMPHREY, LOUISE WANG ZHIYING	
ART UNIT	**PAPER NUMBER**
1648	

DATE MAILED: 01/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/715,729	SOMMADOSSI ET AL.	
	Examiner	Art Unit	
	Louise Humphrey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 October 2004*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-86* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-86* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1, 2, 5-20, drawn to a pharmaceutical composition comprising 2'-branched nucleoside in combination with one or more drugs that directly or indirectly induce a mutation in a *Flaviviridae* at a location other than a mutation of a nucleotide that results in a change from serine to a different amino acid in the highly conserved consensus sequence, XRXSGXXXT, of domain B of the RNA polymerase region, classified in class 424, subclass 1.73.

II. Claims 3, 4, and 5-20, drawn to a pharmaceutical composition comprising 2'-branched nucleoside in combination with interferon, classified in class 424, subclass 9.1.

III. Claims 21-32, drawn to a pharmaceutical composition comprising a 2', 3', and/or 5'-prodrug of a 2'-branched nucleoside in combination with one or more drugs that directly or indirectly induce a mutation in a *Flaviviridae* at a location other than a mutation of a nucleotide that results in a change from serine to a different amino acid in the highly conserved consensus sequence, XRXSGXXXT, of domain B of the RNA polymerase region, classified in class 424, subclass 1.73.

IV. Claims 33, 34, and 37-52, drawn to a method for treating a *Flaviviridae* infection by administering a 2'-branched nucleoside in combination with one or more drugs that directly or indirectly induce a mutation in a *Flaviviridae* at a location other than a mutation of a nucleotide that results in a change from serine to a different amino acid in the highly conserved consensus sequence, XRXSGXXXT, of domain B of the RNA polymerase region, classified in class 424, subclass 9.1.

V. Claims 35, 36, and 37-52, drawn to a method for treating a *Flaviviridae* infection by administering a 2'-branched nucleoside in combination with interferon, classified in class 424, subclass 9.1.

VI. Claim 53, drawn to a method for treating a patient infected with a *Flaviviridae* virus that is resistant to a 2'-branched nucleoside by administering interferon, classified in class 424, subclass 1.41.

VII. Claims 54-65, drawn to a method for treating a patient infected with *Flaviviridae* by administering a 2', 3', and/or 5'-prodrug of a 2'-branched nucleoside in combination with one or more drugs that directly or indirectly induce a mutation in a *Flaviviridae* at a location other than a mutation of a nucleotide that results in a change from serine to a different amino acid in the highly conserved consensus sequence, XRXSGXXXT, of domain B of the RNA polymerase region, classified in class 424, subclass 1.73.

VIII. Claims 66-80, drawn to a method for treating a patient infected with *Flaviviridae* by administering 2'-branched nucleoside, assaying the blood

of the patient to test for sero-conversion from wild type to mutant virus and administering interferon, classified in class 435, subclass 87.

IX. Claim 81, 83 and 85, drawn to a method for assaying a sample suspected of containing a *Flaviviridae* resistant to a 2'-branched nucleoside by contacting the sample containing a *Flaviviridae* nucleic acid with a sequence with a probe having a sequence complementary to the highly conserved consensus sequence of domain B of the RNA *pol* region of *Flaviviridae*, allowing the probe to hybridize and detecting the hybridization, classified in class 435, subclass 6.

X. Claim 82, 84, and 86, drawn to a method for assaying a sample suspected of containing a *Flaviviridae* resistant to a 2'-branched nucleoside by contacting the sample containing a *Flaviviridae* nucleic acid with a sequence with a probe having a sequence complementary to the cytidine at nucleotide 1214 of the RNA *pol* region of BVDV or the cytidine at nucleotide 8443 of HCV, allowing the probe to hybridize and detecting the hybridization, classified in class 435, subclass 6.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are different products. The compositions of Groups I -III comprise different chemical compounds with different structures and modes of action; therefore each product is patentably distinct.

Inventions IV-X are unrelated because they are methods with different modes of operation, with respect to starting materials, physiological mechanisms, protocol procedures, and end products; therefore, each method is patentably distinct.

Inventions (I-III) and (IV-X) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the compositions can be drug candidates for other diseases or disorders, while the compositions comprising of interferon can be used for the treatment of cancer.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter, and require non-coextensive literature and sequence searches even though in some cases the classification is shared, restriction for examination purposes as indicated is proper.

Species Election

This application contains claims directed to the following patentably distinct species of the claimed invention:

Irrespective of which Invention is elected, Applicant is further required to elect one species from genus (A) or genus (B); and additionally, elect one species from genus (C):

(A) one 2'-branched nucleoside from the genus as set forth in claims 5-15;

(B) one chemical formula from the genus as set forth in claims 16-20; and

(C) one prodrug from the genus as set forth in claims 22-32.

Applicant is required under 35 U.S.C. §121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-4 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. §103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louise Humphrey, Ph.D. whose telephone number is 571-272-5543. The examiner can normally be reached on Mon-Fri, 9am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on 571-272-0902.

Louise Humphrey, Ph.D.
17 January 2006

JEFFREY STUCKER
PRIMARY EXAMINER